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|--|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.                        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/540,609                             | 06/27/2005  | Akihide Mori         | 550718-112          | 9184             |
| 27805                                  | 7590        | 04/18/2007           | EXAMINER            |                  |
| THOMPSON HINE L.L.P.                   |             |                      | HALL, DEANNA K      |                  |
| P.O. BOX 8801                          |             |                      | ART UNIT            |                  |
| DAYTON, OH 45401-8801                  |             |                      | PAPER NUMBER        |                  |
|  |             |                      | 3767                |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE |             | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS                               |             | 04/18/2007           | PAPER               |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/540,609 | <b>Applicant(s)</b><br>MORI ET AL. |  |
|                              | <b>Examiner</b><br>Deanna K. Hall    | <b>Art Unit</b><br>3767            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on June 27, 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>October 31, 2005</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray (US 6,830,564).** Gray discloses:

A syringe body 100 including a cylindrical barrel 101 having a needle mounting portion 101RDN on one end and an opening portion 101RO on the other end for receiving a piston 103. A needle 105 mounted on the needle mounting portion and the piston inserted through the syringe body through the opening portion Fig. 1. Restricting means 107 for restricting the movement of the piston so that the cylindrical barrel is prefilled C14 L38-40 with a liquid medicine and then closed by the piston. C15 L18-30.

The piston movement restricting means comprises a bellows 107 and a fixing sheet with the bellows composed of an alternating circumferential portion 107P and trough portion 107W. The bellows cover at least a portion of the piston C18 L63-67 and the fixing sheet is glued onto the circumferential portion of the bellows C15 L25-30.

3. **Claims 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen (US 6,616,640).** Chen discloses:

A cylindrical barrel 20 having a needle mounting portion 22 on one end and an piston-receiving opening 21 on the second end; a needle 30 adapted to be mounted to

the needle mounting portion; and a piston 70 having a hollow inner portion C3 L40.

Said needle may be received within said hollow inner portion C3 L66-67.

A reverse movement stopper ring 81 positioned within said cylindrical barrel for preventing said piston from being withdrawn from said cylindrical barrel after said piston has been advanced through said cylindrical barrel C6 L28-64.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of McMahon (US 5,782,804).**

Gray shows as discussed above. An object of Gray's invention is to prevent contamination C1 L5- C2 L51. McMahon, in the analogous art, teaches a hollow piston rod 6 with an end cap 40 and an opening storage portion wherein the needle is stored Fig. 7. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Gray with the hollow piston and end cap as taught by McMahon for retracting the needle into the hollow piston for storage to prevent contamination Gray C1 L5- C2 L51.

**6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Chen (US 6,616,640).**

Gray shows as discussed above. An object of Gray's invention is to prevent accidental separation of the plunger from the barrel Gray C2 L37-41. Chen, in the analogous art, teaches a reverse-movement prevention stopper ring 81 in the cylindrical barrel of the syringe body and a number of reverse-movement prevention projections 82 arranged on the piston rod wherein the projections are stopped by the stopper ring C4 L8-24. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Gray with the plunger anti-detachment mechanism 80 as taught by Chen for preventing the accidental separation of the plunger from the barrel Gray C2 L37-41.

**7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Crawford (US 4,573,977).**

Gray shows as discussed above. The object of Gray's invention is to inject pre-filled syringes of medication into patients Gray C2 L55-64. Crawford, in the analogous art, teaches a liquid-prefilled pouch 20 arranged in the cylindrical barrel Fig. 1 wherein a proximal sharp end of the needle 14 is projected in the cylindrical barrel Fig. 2. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Gray with the pouch as taught by Crawford for injecting pre-filled syringes of medication into patients Gray C2 L55-64.

**8. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Brignola (US 4,412,836) and Sampson (US 5,098,403).**

Gray shows as discussed above. The object of Gray's invention is to prevent contamination C1 L5- C2 L51. Brignola and Sampson, in the analogous art, teach a closing diaphragm having crossing notches Fig. 18 and a slide cover movable along the barrel of the syringe body Sampson Fig. 2. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Gray with the diaphragm as taught by Brignola and the slide cover Fig. 2 as taught by Sampson for preventing contamination by making the needle retractable Gray C1 L5- C2 L51.

**9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Gray (US 6,830,564).**

Chen shows as discussed above. The object of Chen's invention is prevent accidental injury or re-use of a syringe Chen C1 L9-14. Gray, in the analogous art, teaches a fixing sheet 107, C15 L25-30 removably attached to a piston for preventing unintentional advancement of the piston through the cylindrical barrel. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Chen with the fixing sheet as taught by Gray since adding the fixing sheet to the piston will provide a barrier of movement thus preventing any accidental injury or re-use of the syringe Chen C1 L9-14.

***Conclusion***

Art Unit: 3767

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 8:00am-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deanna K. Hall  
Examiner  
AU 3767

dkh

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

